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Eric Perouse

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EXAMINER

TANNER, JOCELYN C

ART UNIT

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3731

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,489	Applicant(s) PEROUSE, ERIC	
	Examiner JOCELIN C. TANNER	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-24 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the Amendment filed 26 November 2008. Claims 11-24 are currently pending. The Examiner acknowledges the amendments to claims 11 and 19 and the addition of new claims 21-24.

Claim Objections

Claim 16 is objected to because of the following informalities: The claim dependency of claim 16 is absent from the claim. For the art rejections below, claim 16 has been treated as depending from claim 11. Appropriate correction is required.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 11-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Berg et al. (US Patent No. 6,451,048).**

Regarding claim 11, Berg et al. discloses a radially deformable flexible artificial graft or “tubular prosthesis” (FIG. 2, element #30) including a frame or “lattice” (FIG. 4a, element #38) that is inherently deformable between a retracted state of small diameter and an expanded state of greater diameter due to the flexible material, i.e. nitinol, of the frame. A flexible artificial graft or “tubular prosthesis including at least two external wire

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connectors or “hooks” (FIG. 5, elements #34, 40 and 44) defining between them a clamp for hooking in external tissue (column 4, lines 19-21), the two hooks being carried by the lattice (FIG. 5) and due to the wire connectors being formed of the flexible material, nitinol, the wires are movable between a spaced- apart position in which the clamp is open, and a closer-together position in which the clamp is closed.

The recitation “a radially deformable endovascular prosthesis” has been given limited patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. *Kropa v. Robie*, 88 USPQ 478 (CCPA 1951). The device of Berg is being considered a radially deformable endovascular prosthesis because it is capable of being radially deformed and capable of being deployed within the vasculature.

3. Regarding claim **12**, Berg et al. discloses that each wire connector or “hook” is connected to the frame or “lattice” from a connection end (FIG. 5), and the hooks of a given clamp are movable relative to each other during deformation of the prosthesis (column 6, lines 5-7) wherein the wire connectors are loaded into a sheath and radially compressed during installation.

4. Regarding claim **13**, Berg et al. discloses a frame or “lattice” including crossing wires that form meshes in the form of deformable quadrilaterals (FIG. 4a), diamond-

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shaped mesh having four sides, and wherein each hook (FIG. 4a, elements #34) is connected to the lattice in a intersection or “comer” (FIG. 4a, elements #48) of a quadrilateral.

5. Regarding claim **14**, Berg et al. discloses that each wire connector or “hook” (FIG. 4a, element #34) is welded or soldered to the frame or “lattice” at its connection end (column 4, lines 65-68, FIG. 4a).

6. Regarding claim **15**, Berg et al. discloses wire connectors or “hooks” (FIG. 4a, element #34) that are extended at their connection end by a strand that is twisted around a frame or “lattice” (FIG. 4a) wherein the wire connectors are woven or twisted under and over the frame (column 5, lines 2-5).

7. Regarding claim **16**, Berg et al. discloses that each wire connector or “hook” (FIG. 5, element #40 and #44) of a given clamp presents the shape of a shepherd's crook at its hooking end (FIG. 5, element #52), The two wire connectors or “hooks” overlapping at least in part in order to form a clamp (column 4, lines 24-31) wherein the connectors protrude on both sides of the tissue to which the graft is attached, thus forming a clamp in which the extent of overlapping is dependent on the thickness of the tissue. The wire connectors or “hooks” can be curved to varying degrees to match the curvatures needed to make a graft connection (column 6, lines 35-38).

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8. Regarding claim **17**, Berg et al. discloses that each wire connector or “hook” (FIG. 7a, element #34) is in the form of a substantially rectilinear blade, the two hooks extending facing each other and spaced apart from each other when the clamp is open.

9. Regarding claim **18**, Berg et al. discloses a frame or “lattice” (FIG. 4a, element #38) is inherently elastically deformable towards its expanded position due to the flexible material, i.e. nitinol, of the frame or lattice that facilitates contraction and expansion.

10. Claims 11, 12, 17, 18, and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Berg et al. (US PGPub No. 2003/0018377A1 – now US Patent No. 7,087,088).

11. Regarding claim **11**, Berg et al, discloses a band (3302) that may be in the form of “deformable lattice” (100) including a frame that is deformable between a retracted state of small diameter and an expanded state of greater diameter, having at least two external hooks (3310) defining between them a clamp for hooking external tissue, the two balloon-actuated hooks being carried by the lattice are movable between a spaced-apart position in which the clamp is open, and a closer-together position in which the clamp is closed when a balloon disposed between the band is expanded or contracted ([0169-0173], Figs. 3, 33, 34).

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12. Regarding claim **12**, Berg discloses each hook being connected to the lattice from a connection end and the hooks of a given clamp being movable relative to each other during deformation of the prosthesis ([0169-0173], Figs. 3, 33, 34).

13. Regarding claim **17**, Berg et al. discloses that each hook (4300) may be in the form of a substantially rectilinear blade, the two hooks extending facing each other and spaced apart from each other when the clamp is open (Fig. 43).

14. Regarding claim **18**, Berg et al. discloses a lattice that may be elastically deformable towards its expanded position when formed of flexible material, i.e. nitinol [0097].

15. Regarding claim **21**, Berg et al. discloses hooks (3310) having a spaced apart position in the retracted state of the lattice (3300) and a closer-together position when the lattice is in an expanded configuration (Figs. 33, 34).

16. Regarding claim **22**, Berg et al. discloses a lattice (3300) that may have crossing wires defining meshes in the form of lattice (100) wherein hooks (3310) having a spaced apart position in the retracted state of the lattice (3300) and a closer-together position when the lattice is in an expanded configuration ([0169-0173], Figs. 3, 33, 34).

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17. Regarding claim **23**, Berg et al. discloses hooks (3310) that are offset circumferentially with respect to each other around the tubular prosthesis (3300). See figure 33.

18. Regarding claim **24**, Berg et al. discloses hooks (3310) of a clamp having a second circumferential spacing that is farther apart due to expansion of the prosthesis and the formation of a closer-together position of the clamp (Fig. 34).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al. (US Patent No. 6,451,048) in view of Perez et al. (US Patent No. 6,984,244).

Regarding claims **19 and 20**, Berg et al. discloses all of the limitations previously discussed. It is the Examiner's position that a kit is being is interpreted as an assembly of provisions used for treating a blood vessel including a flexible artificial graft or "tubular prosthesis" (FIG. 2, element #30) wherein the frame or "lattice" (FIG. 2, element #38) is inherently deformable towards its expanded position due to the flexible material, i.e. nitinol, of the frame.

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Perez et al teach a medical repair device delivery system wherein a repair device or “tubular prosthesis” is encompassed by a capsule or “holding means” (FIG. 12, element #333) which restrains the repair device and prevents its deployment (column 12, lines 63-64). The repair device is secured by its distal end to an inner catheter or “delivery tube” (FIG. 12, element #320) which restricts the repair device from deployment and delivers the device to the treatment site. The hooks (FIG. 2, element #96) are pressed into the grooves or “channels” (FIG. 14, element #376) arranged within the stop ring or “confinement duct” (FIG. 12, element #370) attached to the distal end of the inner catheter. The capsule prevents the hooks from contacting the sheath assembly (column 12, lines 65-68, FIG. 13, element #340). The hooks are free to imbed in the vasculature once the capsule and sheath assembly are retracted (column 13, lines 12-13).

Because the devices of Berg et al. and Perez et al teach known elements, i.e. engaging means for implantation devices, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have applied the known technique of incorporating grooves within the distal end of the sheath and to secure the wire connectors of Berg et al. within the grooves of the sheath, as taught by Perez et al, for the predictable result of preventing the hooks from piercing the tissue prior to installation.

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20. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al. (US PGPub No. 2003/0018377A1 – now US Patent No. 7,087,088) in view of Berg et al. (US Patent No. 6,451,048).

21. Regarding claim **13**, Berg et al. discloses a lattice including crossing wires that form meshes in the form of deformable quadrilaterals (FIG. 3), a diamond-shaped mesh having four sides. However, Berg et al. fails to disclose hooks attached to the corners of the quadrilaterals.

Berg et al. ('048) teaches a lattice (38) formed of quadrilaterals having hooks (34) to connect to body organ tubing wherein each hook is connected to the lattice in an intersection or "corner" (48) of a quadrilateral. See fig. 4a.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the lattice of Berg et al. with hooks at the corners of the quadrilaterals of the mesh, as taught by Berg et al. ('048), to adequately secure the prosthesis to the organ tubing.

22. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al. (US PGPub No. 2003/0018377A1 – now US Patent No. 7,087,088) in view of Bender et al. (US Patent No. 7,267,682).

23. Regarding claim 16, Berg et al. discloses all of the limitations previously discussed except for two hooks having a shepherd's crook end and overlapping in part to form a clamp.

Bender et al. teaches a staple having ends in the form of a shepherd's hook and overlapping in part to secure tissue of a graft vessel to tissue of a target vessel (Fig. 6).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the hooks of Berg et al. with shepherd's crook ends and the ability to overlap in part to prevent slippage.

24. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al. (US PGPub No. 2003/0018377A1 – now US Patent No. 7,087,088) in view of Berg et al (US Patent No. 6,451,048) in view of Perez et al (US Patent No. 6,984,244).

25. Regarding claims **19 and 20**, Berg et al. discloses all of the limitations previously discussed. It is the Examiner's position that a kit is being interpreted as an assembly of provisions used for treating a blood vessel including a prosthesis (30) having a lattice (38) of crossing wires forming deformable quadrilaterals, and two hooks of each clamp carried by the lattice ([0169-0173], Figs. 3, 33). However, Berg et al. fails to disclose hooks in each corner of the quadrilaterals.

Berg et al. ('048) teaches a lattice (38) formed of quadrilaterals having hooks (34) to connect to body organ tubing wherein each hook is connected to the lattice in an intersection or "corner" (48) of a quadrilateral. See fig. 4a.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the lattice of Berg et al. with hooks at the corners of the quadrilaterals of the mesh, as taught by Berg et al. ('048), to

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adequately secure the prosthesis to the organ tubing. However, the combination of Berg et al. and Berg et al. ('048) fails to disclose a lattice delivery tube defining a duct for confining the prosthesis and hooks in a retracted configuration.

Perez et al teach a medical repair device delivery system wherein a repair device or "prosthesis" is encompassed by a capsule or "holding means" (FIG. 12, element #333) which restrains the repair device and prevents its deployment (column 12, lines 63-64). The repair device is secured by its distal end to an inner catheter or "delivery tube" (FIG. 12, element #320) which restricts the repair device from deployment and delivers the device to the treatment site. The hooks (FIG. 2, element #96) are pressed into the grooves or "channels" (FIG. 14, element #376) arranged within the stop ring or "confinement duct" (FIG. 12, element #370) attached to the distal end of the inner catheter. The capsule prevents the hooks from contacting the sheath assembly (column 12, lines 65-68, FIG. 13, element #340). The hooks are free to imbed in the vasculature once the capsule and sheath assembly are retracted (column 13, lines 12-13).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the devices of Berg et al. and Berg et al. ('048) with grooves within the distal end of the sheath to secure the hooks within the grooves of the sheath, as taught by Perez et al, to prevent the hooks from piercing and injuring the tissue prior to installation.

Response to Arguments

Applicant's arguments filed 26 November 2008 have been fully considered but they are not persuasive. In response to applicant's argument that the prosthesis of Berg et al. ('048) is not an endovascular prosthesis, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The graft structure of Berg et al. ('048) is capable of being used inside a vessel since it is used to connect portions of body organ tubing of any suitable shape which may sized smaller than a blood vessel. Furthermore, if used inside a vessel, the hooks of Berg et al. ('048) have the capability of attaching to the inside surface of the vessel to secure the prosthesis to the lumen even with the formation of a gap.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jocelin C. Tanner/
2/17/2009
Examiner, Art Unit 3731

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